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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,840	07/21/2000	Lance E. Steward	D-2885	4487

7590 09/27/2002

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EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/27/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/620,840	STEWARD ET AL.	
	Examiner	Art Unit	
	Robert Hayes	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, drawn to a modified neurotoxin where in the leucine-based motif comprises SEQ ID NO: 1, classified in class 530, subclass 350, for example.

II. Claims 32-34, drawn to a method for changing the biological persistence of a neurotoxin, classification dependent upon method steps.

III. Claims 35-40 and 42 (each in part), drawn to a method of treating a biological disorder comprising administering an effective dose of a modified neurotoxin to a group of muscles in a mammal, classified in class 514, subclass 2, for example.

IV. Claims 35-39 and 41-42 (each in part), drawn to a method of treating a biological disorder comprising administering an effective dose of a modified neurotoxin to a gland in a mammal, classified in class 514, subclass 2, for example.

V. Claims 35-39 and 42-43 (each in part), drawn to a method of treating a biological disorder comprising administering an effective dose of a modified neurotoxin to the spinal cord in a mammal, classified in class 514, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II, III, IV, and V are directed to methods that are distinct

both physically and functionally, and are not required one for the other. Invention II requires search and consideration of enhancing or reducing the biological persistence of a neurotoxin, which is not required by any of the other Inventions. Invention III requires search and consideration of administering an effective amount of a modified neurotoxin to a group of muscles, which is not required by any of the other Inventions. Invention IV requires search and consideration of administering an effective amount of a modified neurotoxin to a gland, which is not required by any of the other Inventions. Invention V requires search and consideration of administering an effective amount of a modified neurotoxin to the spinal cord, which is not required by any of the other Inventions.

4. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the modified neurotoxin of Invention I can be prepared by processes which are materially different from the method of Invention II, such as by chemical synthesis, or by isolation and purification from natural sources.

5. Inventions I and each of III, IV, and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the modified neurotoxin of Invention I can be used in a materially different process of used in materially different processes other than the

therapeutic methods of Inventions III, IV, and V such as labeling its target enzymes in a biochemical assay.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Botulinum toxin serotype A

b. Botulinum toxin serotype B

c. Botulinum toxin serotype C_1

d. Botulinum toxin serotype D

e. Botulinum toxin serotype E

f. Botulinum toxin serotype F

g. Botulinum toxin serotype G

h. Tetani toxin

i. A mixture thereof

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 11 is generic.

8. If applicant selects Invention I, one species from the Clostridial neurotoxin group must be chosen to be fully responsive.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
September 25, 2002

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600